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510(k) SUMMARY

DEC 17 2004

Tissue Science Laboratories, plc's  
Permacol® Surgical Implant  
Crosslinked Porcine Dermal Collagen Mesh

**Submitter's Name, Address, Telephone Number, Contact Person and Date**

**Prepared:**

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Tissue Science Laboratories, plc  
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Contact Person: Victoria Taylor

Date Prepared: December 06, 2004

**Name of Device and Name/Address of Sponsor**

Tissue Science Laboratories, plc  
7<sup>th</sup> Floor, Victoria House  
Victoria Road  
Aldershot  
Hampshire GU11 1EJ  
United Kingdom

**Common or Usual Name**

Surgical Mesh

**Classification Name**

Surgical Mesh

**Predicate Devices**

Permacol® Crosslinked Porcine Dermal Collagen Surgical Mesh (K992556), Bio-Vascular Inc's Supple Peri-Guard® (K983162), Peri-Guard®(K983162), Cook Biotech's SurgiSIS™ (K980431) and Bard's® CK Parastomal Hernia Patch (K042026).

**Intended Use**

Permacol® Surgical Implant is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the repair of damaged or ruptured soft tissue

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membranes. It is specifically indicated for the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias.

### **Technological Characteristics and Substantial Equivalence**

Permacol® is substantially equivalent to its predicates because it has the same intended use and very similar technological characteristics. Permacol® and its predicates are intended for use in a broad range of surgical procedures for soft tissue repair/reinforcement. Permacol® and Bard's® CK Parastomal Hernia Patch are specifically indicated for the repair of abdominal wall defects and hernias, including parastomal hernias.

The technological characteristics of Permacol® are very similar to its predicate devices. All of the devices also share similar dimensions, technological characteristics, and thickness.

### **Performance Data**

Biocompatibility and bench testing have been completed and support the safety and effectiveness of the Permacol® Surgical Implant for its intended use.

The biocompatibility test results show that the materials used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing Permacol® Surgical Implant will meet the established specifications necessary for consistent performance during their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 17 2004

Ms. Victoria Taylor  
Associate Director of Regulatory Affairs  
Tissue Science Laboratories plc  
North American Division  
1141 Clark Street, Suite D  
Covington, Georgia 30014

Re: K043366

Trade/Device Name: Permacol® Surgical Implant  
Regulation Number: 21 CFR 878.3300  
Regulation Name: Polymeric surgical mesh  
Regulatory Class: II  
Product Code: FTL  
Dated: December 6, 2004  
Received: December 8, 2004

Dear Ms. Taylor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

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## Indications for Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Permacol® Surgical Implant

### Indications for Use:

Permacol® is intended of use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of abdominal wall defects and hernias, including but not limited to parastomal hernias.

Prescription Use  AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Miriam C. Provost*  
(Division Sign-Off)  
**Division of General, Restorative,  
and Neurological Devices**

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